EDGEWOOD

CHEMICAL BIOLOGICAL CENTER

U.S. ARMY SOLDIER AND BIOLOGICAL CHEMICAL COMMAND

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BIO-DETECTOR ASSESSMENT

John D. Walther
ADVANCED PLANNING AND INITIATIVES DIRECTORATE

Peter A. Emanuel
Michael T. Goode
A. Peter Snyder
Jerold R. Bottiger
RESEARCH AND TECHNOLOGY DIRECTORATE

Peter J. Stopa
Gilbert G. Olsen
Kate K. Ong
ENGINEERING DIRECTORATE

Uday J. Mehta
Dennis P. Bolt
Randolph G. Laye
CB SERVICES DIRECTORATE

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Aberdeen Proving Ground, MD 21010-5424

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Walther, John D.; Emanuel, Peter A.; Goode, Michael T.; Snyder, A. Peter; Bottiger, Jerold R.; Stopa, Peter J.; Olsen, Gilbert G.; Ong, Kate K.; Mehta, Uday J.; Bolt, Dennis P.; and Laye, Randolph G.

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The Federal Response Plan charges the Environmental Protection Agency (EPA) with the mission to respond either to spills or releases of hazardous materials and handle health, safety, and clean-up actions. EPA Environmental Response Teams (ERT), serving as technical advisors to On-Scene Coordinators, would like to improve their capability to respond to incidents involving agents of biological origin. To accomplish this, they would need the ability to handle samples in all forms (air, liquid, solid, vegetation) and to quickly perform presumptive analysis with an on-site, portable system. The ERT tasked the U.S. Army Edgewood Chemical Biological Center (ECBC) to provide guidance on how the ERT could implement a biological detection capability to support their decontamination mission under the Federal Response Plan and to also provide a limited analysis capability to support a wider mission. The objective of this report was to evaluate available biological detection and identification devices for their potential to meet EPA program needs, and to recommend the best candidate(s) for further testing. A structured decision analysis approach was followed to perform the assessment. A complementary layered approach, combining different devices and technologies, was ultimately recommended.

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PREFACE

The work described in this report was authorized under the interagency agreement between the Environmental Protection Agency and U.S. Army Edgewood Chemical Biological Center. This work was started in March 2001 and completed in December 2001.

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BIO-DETECTOR ASSESSMENT

This report describes the Bio-Detector assessment that the Edgewood Chemical Biological Center performed for the Environmental Response Team. The document is composed of seven parts:

1) *Background* – a brief summary of the objective and requirements of the study.
2) *Process Description* – a description of the approach and evaluation methodology that was followed to conduct the study.
3) *Bio-Detector Devices* – a listing of the devices that were considered for assessment.
4) *Evaluation Model* – a description of the criteria that were used to evaluate the devices.
5) *Evaluation Results* – information on how the devices rank based on the evaluation, including a discussion of technology strengths and weaknesses.
6) *Conclusions and Recommendations* – a proposed approach to meet the stated objectives, based on analysis of the results.
7) *Appendices* – various information such as a listing of study participants and more detailed analysis of the results.

1. BACKGROUND

The Federal Response Plan charges the Environmental Protection Agency (EPA) with the mission to respond to spills or releases of hazardous materials and handle health, safety, and clean-up actions. EPA Environmental Response Teams (ERT) would serve as technical advisors to On-Scene Coordinators for these incidents. The ERT identified two scenarios, Decontamination and Identification, to describe their responsibilities. Decontamination has the highest priority and has the objectives of determining effectiveness of the decontamination operation as well as the impact to the environment from decontamination operations. The identification scenario is defined as a confirmation of prior analyses.

The ERT would like to improve their capability to respond to incidents involving agents of biological origin. To accomplish this, they would need the ability to handle samples in all forms (air, liquid, solid, vegetation) and to quickly perform presumptive analysis with an on-site, portable system. The ERT tasked the US Army Edgewood Chemical Biological Center (ECBC) to provide guidance on how the ERT could implement a biological detection capability to support their decontamination mission under the Federal Response Plan and to also provide a limited analysis capability to support a wider mission.

The objective of the ERT Bio-Detector assessment was to evaluate available biological detection and identification devices for their potential to meet EPA program needs, and to recommend the best candidate(s) for further testing. The study was structured to address the two scenarios described above, resulting in separate assessments being performed for Detector and Identifier devices.

2. PROCESS DESCRIPTION

A structured decision analysis process was developed for this study. The approach has been used for numerous similar efforts at ECBC. At its core is the identification of important factors, or mission essential criteria, against which candidate devices are evaluated. The process includes thorough documentation of the results and the associated rationale so that final results and recommendations can be readily explained and defended.

The process is summarized below:

1. Formation of study team – The study team consisted of three groups of participants:

    - Customer (ERT) representatives – These participants were responsible for articulating customer objectives, needs, and requirements.
    - Technical subject matter experts (SME's) – These participants, referred to as the evaluation panel, have detailed knowledge of the devices (and the technologies upon which they're based) that were evaluated. They also support similar missions within ECBC and have an understanding of operational necessities.
    - Decision Analysis Team (DAT) – The DAT guided the study team through the process. This included the conduct of evaluation meetings and the evaluation and documentation of results.

    The study team participated in evaluation meetings that were facilitated by the Decision Analysis Team. A laptop computer and projector were used to focus the participants' deliberations and to document information during the evaluation meetings. All decisions were made by consensus. The members of the study team are listed in Appendix A.

2. Identify and describe candidate devices – The devices that had potential to meet customer needs were identified. Detailed descriptions of the devices, to include technical capabilities and level of maturity, physical characteristics, and operational considerations were also obtained and provided to the study team. The devices that were considered are listed in Section 3 of the report.

3. Develop evaluation model – An evaluation model was developed to evaluate the devices. The core of the model was the evaluation criteria that were derived from customer needs/requirements. Definitions and performance scales were developed for each criterion. The model and how it was developed are described in Section 4 of the report.

4. Evaluate the candidate devices – The candidate devices were scored against all criteria, using the performance scales. The technical subject matter experts first individually scored the candidates, and then convened as an evaluation panel to do consensus-based scoring. The assessments were based on available data, as well as the experience and expertise of the panel members. A decision support software tool, Logical Decisions for Windows (LDW), was used to develop and document the evaluation model, elicit and capture weights and scores, and to aid in the analysis of results.

5. Analyze results – LDW generated rankings that are based on the technology scores and the criteria weights. Each candidate device was analyzed for individual strengths and weaknesses, and the results were summarized. Sensitivity analysis was also performed to determine which factors had the greatest impact on the results. The results and related analysis is contained in Section 5 and Appendix C of the report.

6. Document results and recommendations – The analysis of results led to the recommendations that are provided in Section 6 of the report.

3. BIOLOGICAL DETECTION DEVICES

A literature search was conducted to identify devices that had the potential to meet EPA needs. Descriptions of each device were prepared and provided to the study team (those descriptions are available as a separate document). The devices were grouped according to whether they were detectors or identifiers.

In this context, detectors are devices that can be used to determine if a material is of biological origin. To accomplish this, the device may detect the presence of DNA, protein, or adenosine tri-phosphate, which is the energy source in the cell. The presence of any one or several of these markers suggests that the material could be of biological origin. Additionally, these detection devices can be used to determine if the biological material in the sample is live (viable). This viability issue is important for decontamination issues.

Within the identification category, the devices were described as being immunoassay-based or nucleic acid-based technologies.

Immunoassay technology is based on the use of antibodies that target proteins unique to a biological agent. It has been used as a field analysis technique in both clinical and environmental roles for many years. Rapid immunoassays have been used since the early 1980's to directly detect microbiological agents in clinical specimens. The 1990's saw application of this technology to environmental uses, including pesticide analysis.

Nucleic acid-based technologies accomplish detection and identification through the targeting of nucleic acids, usually DNA, of biological agents. It was developed during the mid-1980's as a clinical analysis technique and its uses are still expanding. The technology offers the most specific and sensitive analysis for microbiological materials in environmental samples; however, it is also the most prone to interferences that may be present in the sample.

Several devices were eliminated from consideration for various reasons, such as lack of availability. The evaluation panel noted that biological analysis in the field is a rapidly growing area, and that what is not available today may well be the optimal device in the near future.

The following devices were evaluated:

Detectors

- BIOHAZ
- FACSCount
- LUMINEX 100

Identifiers, Immunoassay-based

- ANALYTE 2000
- BioDetector (BD)
- BIOHAZ with New Horizon Tickets
- FACSCount
- Handheld Assays
- LUMINEX 100
- ORIGEN Analyzer
- Tetracore Tickets

Identifiers, Nucleic acid-based

- CEPHEID SMART CYCLER
- RAPID ™ SYSTEM

The following devices were not evaluated due to lack of availability at this time:

- 4WARN2
- ANDCARE RAPID GENE DETECTION
- Handheld Advanced Nucleic Acid Analyzer (HANAA)
- Medtox Test tickets for non-proteinaceous toxins.

These devices were also not evaluated, for the reasons listed:

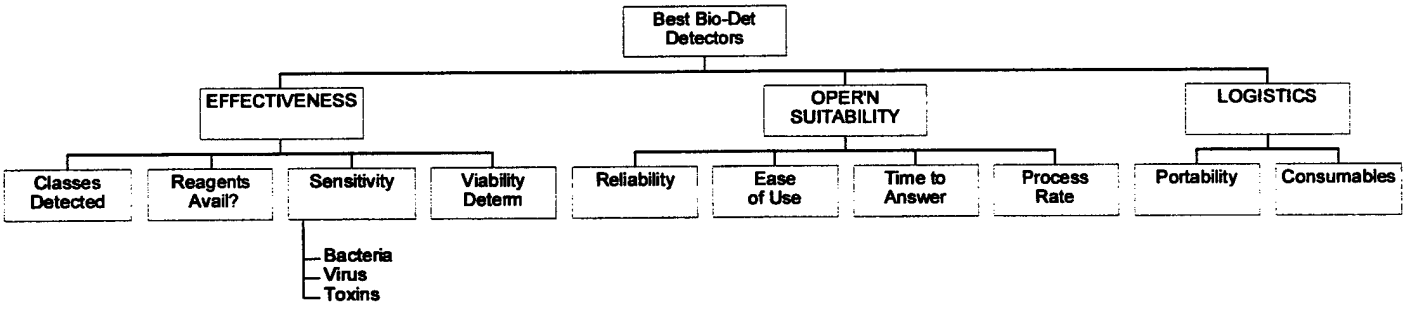
- 4WARN - considered to be an aerosol detector and not applicable to the mission.
- BIOCAPTURE BT-550 - Aerosol sampler w/test tickets - refer to Handheld Assays results.
- Guardian BTA Test Strip Reader System - it is a reader that is associated with Tetracore tickets and is not a stand-alone technology.
- RAPTOR – similar to ANALYTE 2000

4. EVALUATION MODEL

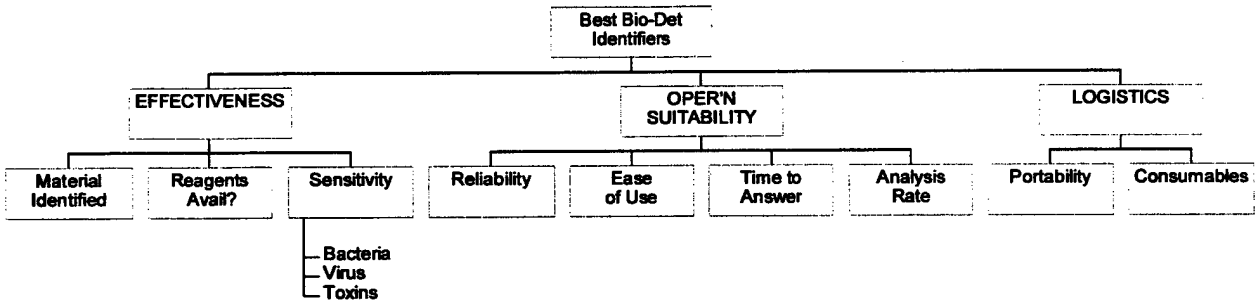
The foundation of the evaluation model is the evaluation criteria. These criteria encompass the factors that most significantly impact the mission, and serve to differentiate the competing candidate technologies. The criteria were derived from ERT requirements. The model was developed over a period of time, on an iterative basis, as study team members discussed technology capabilities and ERT's needs. Having all team members participate in criteria development ensured that customer needs were expressed in realistic terms given the capabilities and limitations of available technology.

The criteria were structured as a hierarchy. There were three criteria categories: Effectiveness, Operational Suitability, and Logistics. Each category was further broken down into several evaluation criteria. The Sensitivity criterion was further split into three sub-criteria. The criteria were somewhat different depending on whether the evaluated device was a detector or identifier, which resulted in two separate evaluation models, as shown below.

Detector Model



Identifier Model



For each criterion, definitions and performance scales were developed. The scales served as the rating scheme, and represented the different levels of performance that could be expected for each criterion. The levels were assigned values ranging from 0 to 100. Two types of scales were developed. Most criteria used a scale with defined discrete levels (shown below for Portability) in which devices were assessed as meeting one of several levels. Some criteria used a continuous scale (shown below for Reliability) in which the score could be any value from 0 to 100.

- Portability:
  - 100 Hand-held
  - 80 Man portable
  - 50 Vehicle required
  - 0 Not portable

- Reliability
  - 100 Less likely to produce false positive or negative; supporting data available
  - 50 Moderate chance of producing false positive or negative; minimal data available
  - 0 More likely to produce false positive or negative; no data available

The final step in model development was to weight the criteria. The study team weighted the criteria by direct assessment. The weighting approach involved distributing 100 points between the lowest level criteria (12 criteria for the detector model, 11 for the identifier model).

The final evaluation model, including criteria definitions, scales, and weights, is presented in Appendix B. Criteria that were not included in the evaluation are also discussed.

Note that acquisition cost for the devices is evaluated separately, as discussed at the end of Section 5.

5. EVALUATION RESULTS

The evaluation panel assessed the technologies by scoring each candidate device against each criterion, using the performance scales. The LDW software was used to capture the consensus scores, multiply the score on each criterion by the criterion weight, and then summing over all criteria to generate an overall score. The overall scores were used to generate rankings, which was a starting point for the analysis of the results. LDW generates a number of graphs and charts to help analyze the results and perform sensitivity analysis to determine which factors have the most impact on the results. Each candidate device was analyzed to assess individual strengths and weaknesses.

This section summarizes the results. The results are presented for the detector devices first, then the identification devices.

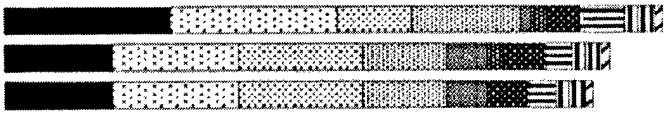
5.1 DETECTORS

The chart below shows the spreadsheet of scores for the three detector devices. Note there is no discrimination among the devices for Process Rate, Portability, and Consumables.

Criterion (wt) / Detector	Classes Detected (.20)	Reagents Avail? (.05)	Bacteria Sens (.05)	Virus Sens (.05)	Toxins (.05)	Viability Deter (.20)	Reliability (.15)	Ease of Use (.15)	Time to first answer (.05)	Process Rate (.02)	Portability (.02)	Consum-ables (.01)
BIOHAZ	Four	100	100,000	10,000K	100	100	90	60	80	20 or more	Man port	Low cost
FACSCount	Three	65	1,000	10,000K	none	75	70	100	100	20 or more	Man port	Low cost
LUMINEX 100	Three	65	1,000	None	none	75	70	100	100	20 or more	Man port	Low cost

The resulting overall scores and rankings for the detector devices are shown in the chart below.

Detector	Score
BIOHAZ	80
FACSCount	73
LUMINEX 100	71



Classes Detected
Reliability
Time to first answer
Portability
Viability Deter
Bacteria Sens
Toxins Sens
Process Rate
Ease of Use
Virus Sens
Reagents Avail?
Consumables

This chart shows how each device scored, both overall and relative to each criterion. The width of the sub-bars indicates the weight of the criterion. For example, since the EPA's focus is on decontamination, Classes Detected and Viability Determination were the highest weighted criteria, and contributed significantly to each device's overall score. However, Biohaz scored highest on these criteria and thus received a greater contribution to overall score than did the other devices.

The results show that the Biohaz has the best overall score, and has the best performance for all but three criteria. Sensitivity analysis was performed to see how the results would be affected by varying the criteria weights. This analysis showed that the overall rankings would not be affected by any reasonable weight changes. Charts that depict this graphically are contained in Appendix C.

No detector device did particularly well for Virus Sensitivity and Toxin Sensitivity. This is based on the sensitivity requirements that were developed by the US military for the battlefield, and may not be appropriate for EPA applications.

5.2 IDENTIFIERS

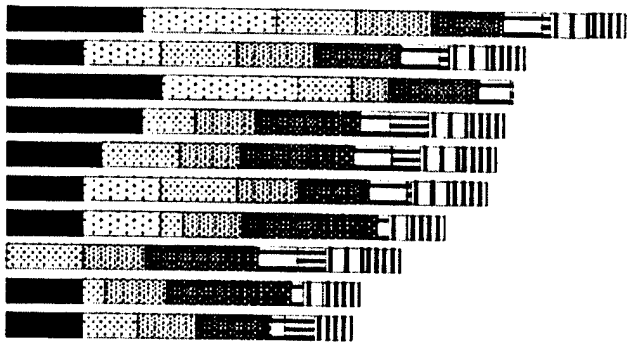
The chart below shows the scores for the identifier devices.

Criterion (wt) / Identifier	Mater ID'd (.20)	Reagents Avail? (.20)	Bacteria Sens (.05)	Virus Sens (.05)	Toxins (.05)	Reliability (.10)	Ease of Use (.10)	Time to first answer (.05)	Analysis Rate (.05)	Portability (.10)	Consum-ables (.05)
ANALYTE 2000	Four	none	100,000	100,000K	1.0	80	70	40	20 or more	Man port	Hi cost
BioDetector (BD)	Eight	seven	100,000	100,000K	100	100	70	80	less than 5	Vehicle	Hi cost
BIOHAZ w/ NHD	Four	four	100,000	none	100	80	100	100	20 or more	Man port	Low cost
CEPHEID SMART CYCLER	Four	none	1,000	1,000K	none	80	30	30	20 or more	Man port	Med cost
FACSCount	Five	none	1,000	10,000K	1.0	80	100	100	20 or more	Man port	Low cost
Handheld Assays	Seven	seven	100,000	none	10	80	100	100	20 or more	Hand	Low cost
LUMINEX 100	None	none	1,000	none	1.0	100	100	100	20 or more	Man port	Low cost
ORIGEN Analyzer	Seven	none	10,000	10,000K	.1	80	70	80	20 or more	Man port	Low cost
RAPID SYSTEM	Four	four	1,000	1,000K	none	90	30	30	20 or more	Man port	Med cost
Tetracore tickets	Four	four	100,000	none	10	100	100	100	20 or more	Hand	Low cost

Note that Reliability and Analysis Rate were not significant discriminators. For Reliability, all devices scored 80 or above. For Analysis Rate, all but one device (BioDetector) can process 20 or more samples in an hour.

The resulting overall scores and rankings for the identifier devices are shown in the chart below. Immunoassay-based devices are denoted by "IA" at the end of their name, and nucleic acid-based devices are denoted by "NA".

Identifier	Score
Handheld Assays Id-IA	80
Tetracore tickets Id-IA	68
BioDetector (BD) Id-IA	66
ORIGEN Analyzer Id-IA	65
FACSCount Id-IA	64
BIOHAZ w/ NHD Id-IA	63
RAPID SYSTEM Id-NA	57
LUMINEX 100 Id-IA	52
CEPHEID SMART CYCLER Id-NA	47
ANALYTE 2000 Id-IA	46



Mater ID'd
Portability
Virus Sens
Consumables
Reagents Avail?
Reliability
Time to first answer
Analysis Rate
Ease of Use
Bacteria Sens
Toxins

Material Identified (Mater ID'd) and Reagent Availability (Reagents Avail?) had the most significant impact on the results due to their weight (combined 40% of the model) and the range of scores amongst the identifier devices.

Handheld Assays had the highest overall score because of its relatively high score for Material Identified and Reagent Availability, and high scores across most of the remaining criteria. Its shortcomings included Bacteria, Virus, and Toxin Sensitivity, but those factors were relatively low-weighted.

Tetracore tickets are comparable to Handheld Assays with the exception of having lower scores for Material Identified (ID'd) and Reagent Availability. This is because Tetracore has four tickets available for biological agents while the Handheld Assays have seven. However, the performance of both systems should be similar.

The BioDetector scored highest of all identifiers for the two most important criteria (Material Identified and Reagent Availability), but its overall score was reduced by relatively poor performance in other areas, such as the three Sensitivity criteria, Portability, Consumables, and Analysis Rate. It was also felt that this particular technology may not be suitable for this application since it was designed for aerosols and may clog when dirtier samples are introduced.

Origen and FACSCount had fairly high scores over most criteria, but lack of Reagent Availability was a significant problem that lowered their overall scores. Origen does score the highest for Toxin Sensitivity.

Of the two nucleic acid-based devices, the Rapid System scored highest, primarily because of higher Reagent Availability than the Cepheid. Both devices had the lowest scores for Ease of Use, Time to First Answer, and Toxin Sensitivity. This is because nucleic acid analysis techniques require extensive sample preparation and may be prone to interferences, such as inhibitors for the PCR reaction that may be present in the sample. Both scored among the highest for Bacteria Sensitivity and Virus Sensitivity. Appendix D contains a chart that directly compares and contrasts these two devices.

Sensitivity analysis was also performed for the identifier devices. The overall results and rankings would not be affected by any reasonable criteria weight changes.

Appendix D contains an LDW chart that compares the highest scoring immunoassay-based device (Handheld Assays) and the highest scoring nucleic acid-based device (Rapid), to show how their strengths and weaknesses are complementary. Handheld Assays are easier to use and use less consumables, while the Rapid provides higher sensitivity for Bacteria and Viruses. This forms the basis for certain recommendations discussed in Section 6.

Appendix E contains acquisition cost information for the detector and identifier devices, expressed as a benefit - cost relationship, derived by dividing the device score by its cost.

6. CONCLUSIONS AND RECOMMENDATIONS

The ERT has multiple requirements in their two scenarios. No single device will be able to meet all requirements; each one has its strengths and weaknesses. As a result, a complementary layered approach is recommended that combines different devices and technologies. The basic recommended approach is to screen with a generic detector, then use an immunoassay device in tandem with a nucleic acid analysis technique (PCR) for identification. This provides the widest possible utility and capability and lends credibility and confidence to field data. The specific approach is described below.

Generic detection will add fidelity to the identification technologies and can be employed first in order to determine if a biological agent is even present. In addition it will allow for the detection of biological materials that are outside the library of identification tools, such as may occur if a new emerging biological agent is in question or if the agent that is used is not usually considered as a classical BW agent. Most of the identification technologies focus on what are considered military threats – a terrorist has a wider library of potential threat agents, although their efficacy may be questionable.

Using the evaluation model developed for this study, the BioHaz Detection system received the highest score in the generic detector category. The evaluation panel also felt that the BioHaz's four sampling kits (SWIPE 1, 2, 3, and 4), designed for taking samples from

surfaces, soil, liquids, and air, are an important component of that system. This system can play several roles in the EPA mission. It can be used to screen for the presence of these materials in suspect samples and can also be used to provide a means to quality control decontamination operations, which is of chief concern to the EPA.

Assuming that the generic screen technique detects a signature that may indicate the presence of a biological agent, an immunoassay device could then be employed for presumptive identification. This is a mature technology with an extensive commercial base that is reflected in the fact that the top rated choices from the technology down-select utilize antibody-based assays. Immunoassay systems are inexpensive, easy to use, fairly rapid, often do not require extensive sample preparation, and are the best choice for the detection of protein toxins such as ricin and botulinum toxin. System sensitivities vary depending on the format and may not approach the sensitivity provided by apparatus that target and amplify the nucleic acid component of an organism.

Using the evaluation model developed for this study, the Handheld Assays received the highest score of all the immunoassay-based devices evaluated. This system utilizes hand-held immuno-chromatographic assays that are strip-based antibody tests similar in design to home pregnancy tests. These assays are available for an expanding library of agents that could be used as biological weapons. One potential shortcoming that needs to be addressed is that these reagents are only available through the military and may have limited availability to non-DOD users. However, there are kits that are commercially available (Tetracore and New Horizons) that have similar performance capabilities, though with a smaller library of target agents.

The third and final system recommended is nucleic acid-based. Systems that utilize PCR and fluorescence-based detection of nucleic acid hybridization can detect and identify bacteria and viruses that carry DNA within them, assuming that no inhibitors were introduced into the analysis. These systems may be able to detect residual DNA that binds to toxin preparations, such as botulinum toxin, if the toxin sample has not been subjected to conditions that may cause extensive degradation or removal of the contaminant DNA. This technology is exquisitely specific and sensitive and is usually not prone to false positives. Detection strategies are designed so that multiple locations within the genomes of a bio-threat agent are targeted. This increases the confidence of the identification and may even be able to provide information on the virulence of the biological agent, if the appropriate genes are present and probed for. Thus, PCR can differentiate a vaccine strain from a weapons strain of *Bacillus anthracis* and can confirm that antibody-based tests were accurate in their results. PCR technology is becoming more widely applied in field applications as ruggedized units have become commercially available. However, this technology does require significant sample preparation and can be inhibited by some environmental contaminants.

Using the evaluation model developed for this study, the RAPID™ received the highest score in the category of PCR-based devices. A number of freeze-dried PCR assays which target the DNA or RNA of biological weapons are already available and that number is expected to grow significantly during the next two years. The system can operate from a battery and can link up with the internet giving the RAPID an autonomous web based ability to transmit data to remote sites for sharing with subject matter experts not collocated with the response teams. The

RAPID ™ requires a sample preparation capability that has been developed by ECBC for other customers for use in the field. This system is also used by the Biological Analysis Teams (BAT) that was established by the US Air Force.

The generic detector, immunoassay, and PCR devices should be combined together to form the core of the ERT biological detection capability. In this approach, a great many factors have been considered, including the complementary information of each of the technologies with one another, the wide array of tasks that may come into play, and the time and technical considerations that a field team is likely to encounter when dealing with a series of unknown samples. The final decision for technologies can be supported by a decision based methodology manual specific for the ERT concept of operations. Training in these systems could augment that ERT based methodology and would provide the EPA's Emergency Response Teams with a biological capability of sufficient scope to meet their objectives.

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APPENDIX A

STUDY TEAM MEMBERS

Customer (EPA-ERT) Representatives

Harry Compton
Rod Turpin
Phil Campagna
David Mickunas
Geoffrey Betsinger

Technical Subject Matter Experts (Evaluation Panel)

Jerry Bottiger, Ph.D.
Peter Emanuel, Ph.D.
Michael Goode
Gil Olsen
Kate Ong
Peter Stopa, Ph.D.
Peter Snyder, Ph.D.

Project Management/Customer Interface

Dennis Bolt
Randy Laye
Uday Mehta

Decision Analysts

John Walther
Valerie Outlaw Lee

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APPENDIX B

EVALUATION MODEL

The criteria are grouped into three major categories: Effectiveness, Operational Suitability, and Logistics. Each category has two to four sub-criteria. Some evaluation criteria are specific to either detection or identification, resulting in two separate models. Weights are shown in parentheses; a "D" indicates the weight applies to the Detector model, an "I" indicates the weight applies to the Identifier model, while no designation means the weight is the same for either model.

EFFECTIVENESS – How well the detector performs (technical characteristics).

1. Number of Classes Detected or Materials Identified

A. Number of Classes Detected (.20, D): Number of different biological classes the devices can detect (the classes listed below are listed in priority order). *This criterion is used only for the devices classified as detection devices.*

100	Sporulated Bacteria, Vegetative Bacteria, Toxins, and Viruses
65	Three classes
35	Two classes
0	One class

B. Number of Biological Materials Identified/Assays Developed (.20, I): The number of different biological agents that can be identified by the device, using the following generally accepted bio agents (traditional agents, commonly accepted weaponized DoD targets) as a baseline:

NOTE – the specific agents used as the reference for the evaluation have been removed from the report to avoid potential information classification issues. The specific agents that can be identified by specific devices can be obtained from the study sponsor.

This criterion is used only for the devices classified as identification devices.

100	All eight
87	Seven
75	Six
62	Five
50	Four
37	Three
25	Two
12	One
0	None

1. **Reagent Availability**

"Available" means through commercial or government (JPO) sources, in some substantial quantities, in the form of a completed end item. For detector devices, the scale is the same as 1A **(weight of .05)**, for identification devices, the scale is the same as in 1B **(weight of .20)**.

2. **Sensitivity**: The minimum amount of BW agent that must be present for the device to make a positive detection and/or identification.

3a. **Bacteria (.05)**

100	1,000 CFU/mL
75	10,000 CFU/mL
25	100,000 CFU/mL
10	1,000,000 CFU/mL
0	No detection

3b. **Toxins (.05)**

100	0.1 ng/mL
75	1.0 ng/mL
25	10 ng/mL
10	100 ng/mL
0	No detection

3c. **Viruses (.05)**

With the exception of BioDetector data is based on MS2 virus simulant.

100	10,000 PFU/mL
85	100,000 PFU/mL
70	1,000,000 PFU/mL
40	10,000,000 PFU/mL
10	100,000,000 PFU/mL
0	No detection

3. **Viability (.20, D)** – ability to determine presence of "dead or live" organisms.
This criterion is used only for the devices classified as detection devices.

100	detects viability of 4 classes
75	detects viability of 3 classes
50	detects viability of 2 classes
25	detects viability of 1 class
0	detects no viability

OPERATIONAL SUITABILITY – Ability to operate the detector in the field, including impact on operations.

5. **Reliability (.15 D, .10 I)** - tendency for the identification devices to provide false positives or false negatives.
   Scores based primarily on expert judgement, as little actual data is available.

100	Less likely to produce false positive or negative; supporting data available
50	Moderate chance of producing false positive or negative; minimal data available
0	More likely to produce false positive or negative; no data available

6. **Ease of Use (.15 D, .10 I)**: The number and complexity of steps required to collect and prepare the sample and perform the assay. Intended user assumed to have a technical bachelor's degree with training.

100	Low opportunity for error (e.g., minimal number of steps)
60	Medium opportunity for error
0	High opportunity for error (e.g., significant number of complex, hand-manipulated operations)

7. **Time to first answer (.05)**: The time required to unpack the detector and have it operational in the field, prepare and analyze one soil sample (soil is the most extreme situation) against four agents to yield a response. Includes instrument equilibration and reconstituting reagents.

100	≤ 30 minutes
80	> 30 minutes to 1 hour
60	> 1 hour to ≤ 2 hours
40	> 2 hours to ≤ 3 hours
20	> 3 hours to ≤ 4 hours
0	> 4 hours

8. **Rate (Process Rate for detectors (.02), Instrument Analysis Rate for identifiers (.05))**: The number of soil samples (worst case) that can be assayed per hour, not including sample prep.

100	20 or more samples per hour
50	10-20 sample per hour
25	5-9 samples per hour
0	less than 5 samples per hour

LOGISTICS – Support required to transport, set-up, and operate the device in the field.

9. **Portability (.02 D, .10 I)**: Ease of transporting the detector to the field and moving and operating the unit. Includes device and operational supplies (i.e., the detector, sampler, required kits, other support equipment). *Note - All devices will require some protective operational environment (50-80 deg F)*

100	Hand-held
80	Man portable
50	Vehicle required
0	Not portable

10. **Consumables (.01 D, .05 I)** - The cost of reagents and support supplies (sampling kits, plastic tubes, etc.) to perform one assay for one agent (including sample prep and clean-up, not including sample acquisition). The devices will require different number of assays.

100	Low $20
50	Medium
0	High >$50

****

11. **Overall Instrument Cost:** cost of instrument and sampler, if necessary.
This is assessed separately (not part of the evaluation model); see Appendix E.

****

The following criteria were eliminated from the evaluation model; the rationale is *italicized*:

Specificity: Bacteria vs. Aerosol: The ability of the detector to identify the specific BW agent versus detecting an aerosol in the sample only.

100	Specific agent detection
60	Agent classification (bio/virus/toxin)
0	Aerosol detection only

Specificity is defined towards aerosols as most likely seen on the battlefield, and is covered by other factors in the model. Aerosol detection is where most of these devices have been used, to date.

Technical Field Support: Availability of technical support (engineering and scientific support) when the detector is in the field.

100	Immediate on-site assistance available
80	Remote diagnostic assistance via phone
60	Delayed on-site assistance
40	Internet web site
0	No assistance likely

Off-site assistance may be available through the Web; not vendor specific. There is not enough information available about the vendors to determine the type of support available, although the subject matter expert panel felt that all devices will have at least minimal support available (perhaps phone).

Durability: ability of the instrument to consistently perform its intended functions (mobile lab in a field setting).

100	can be fully operated in a non-protected environment
80	can be fully operated out the back of a small van
0	requires lab type setting

The subject matter expert panel felt all the devices were comparable in terms of Ruggedness or Durability (packaging design should resolve any concerns), so this criterion would not help to discriminate between the alternative devices.

Power: The type of power required for the detector.

100	No power required
90	Battery powered
60	110 VAC power source required
0	Power from support vehicle 220 volt; special power requirements

The subject matter expert panel felt the devices were comparable in that most will operate on vehicle or separate battery power.

Ability to process various sample types (air, liquid, soil).
Addressed sufficiently in Time to First Answer and Reliability.

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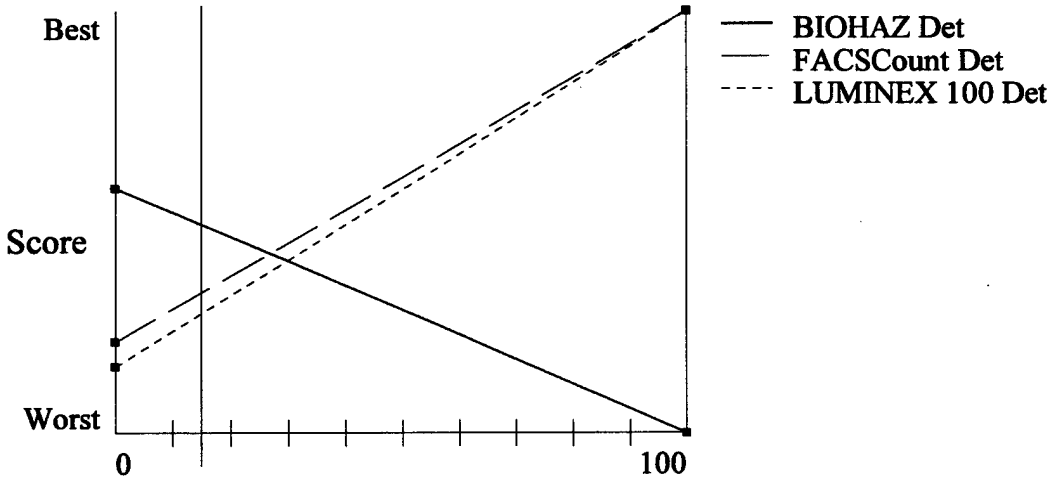
APPENDIX C

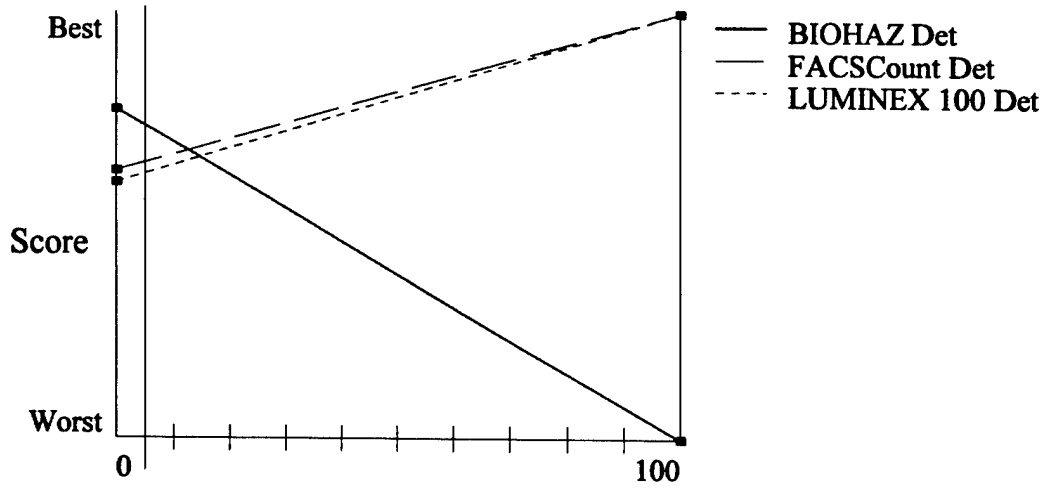
SENSITIVITY CHARTS FOR DETECTORS

The three charts below show the sensitivity analysis for the criteria where Biohaz did not score highest (Ease of Use, Bacteria Sensitivity, and Time to First Answer). For each chart, the relative overall ranking, given the current weighting, is shown where the vertical line (representing the current weight) intersects each of the three device lines.

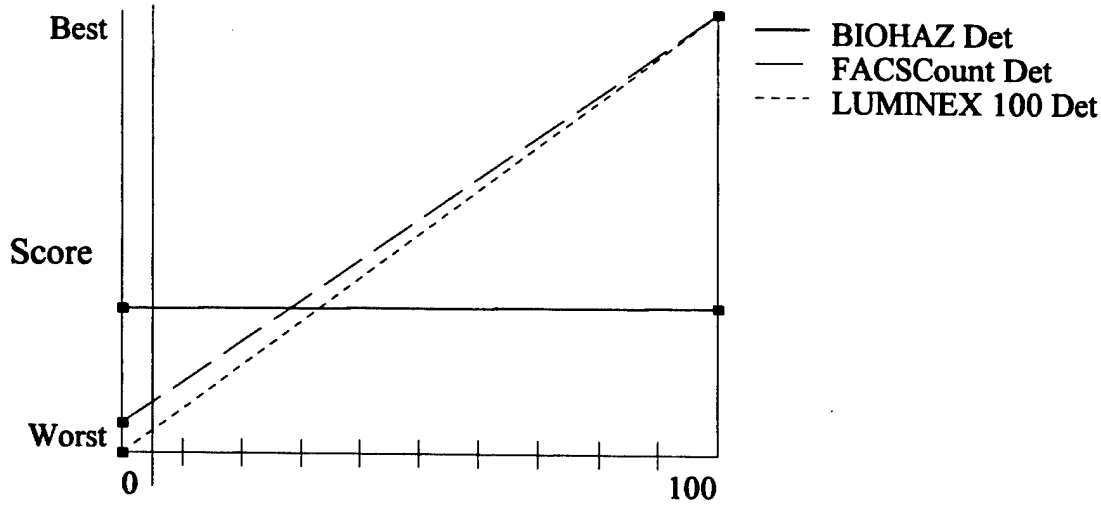
Ease of Use was the most sensitive, but the weight would have to be increased from 15% to 25% (seen by shifting the vertical weight line to the right) before the overall results change. Bacteria Sensitivity would have to more than double its current weight of 5% before FACSCount would be preferred overall. Time to First Answer would require an unrealistic increase to change the overall results.



Percent of Weight on Ease of Use Measure



Percent of Weight on Bacteria Sens Measure



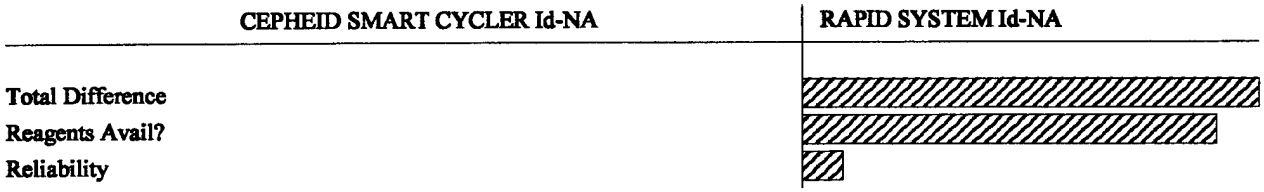
Percent of Weight on Time to first answer Measure

APPENDIX D

SENSITIVITY CHARTS FOR IDENTIFIERS

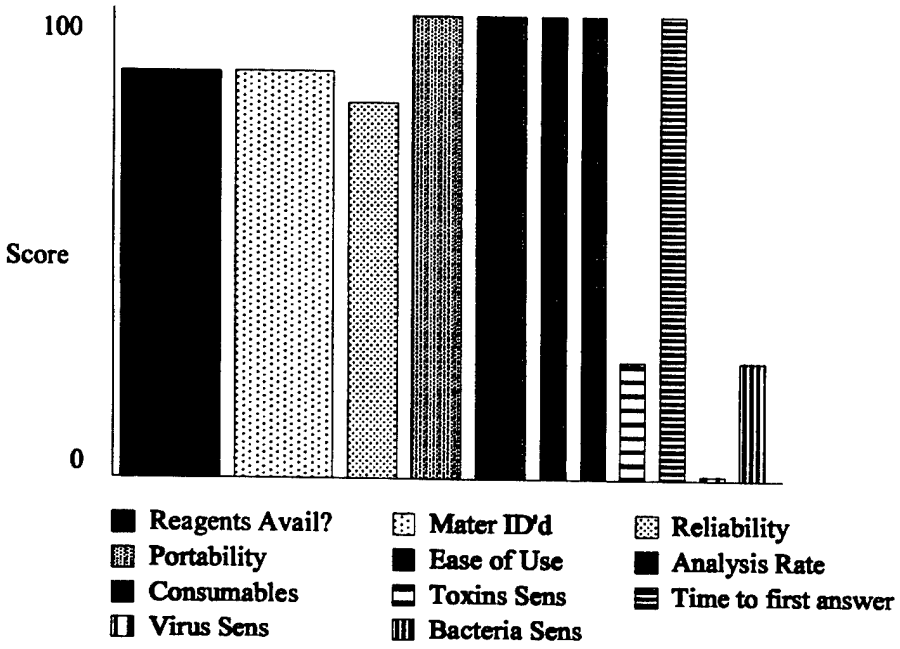
The chart below directly compares the Rapid and Cepheid devices. The only difference in the scoring was Reagent Availability and Reliability.

Overall Score for	RAPID SYSTEM Id-NA	57
	CEPHEID SMART CYCLER Id-NA	47
	Difference	11

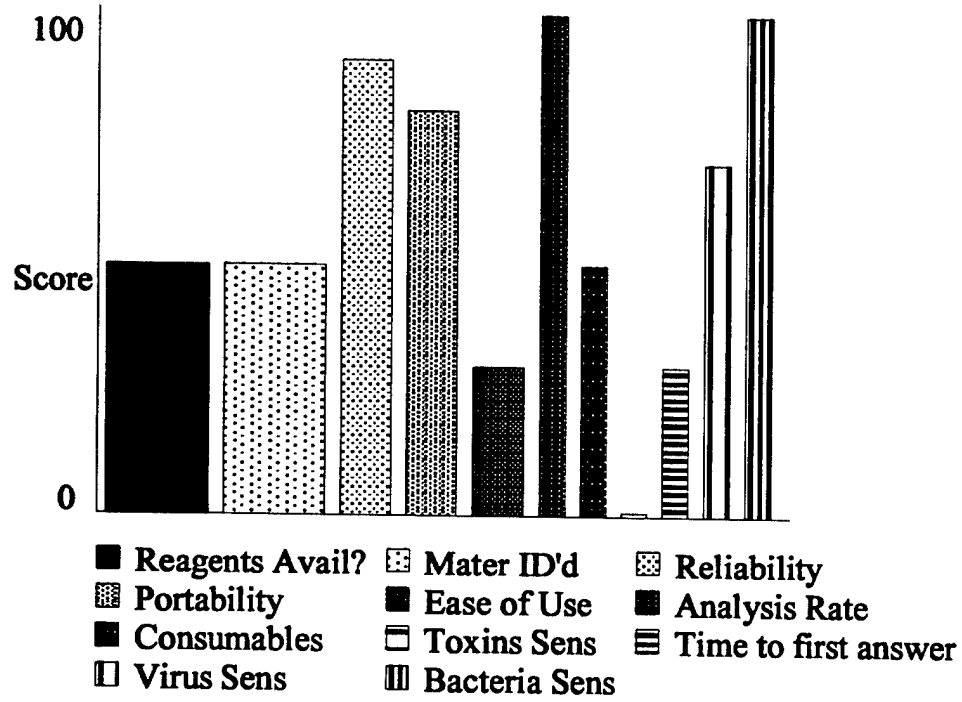


The two charts below compare the highest scoring immunoassay-based device (Handheld Assays) and the highest scoring nucleic acid-based device (Rapid), to show how their strengths and weaknesses are complementary. Handheld Assays are easier to use and use less consumables, while the Rapid provides higher sensitivity for Bacteria and Viruses.

Measure Scores for Handheld Assays Id-IA for BEST BIO DET Identifier Goal



Measure Scores for RAPID SYSTEM Id-NA for BEST BIO DET Identifier Goal



APPENDIX E

BENEFIT - COST ASSESSMENT

This table provides a comparison of each device's "benefit" (the score from the assessment) relative to the acquisition cost. Note the cost does not include consumables.

Within each category, the devices are listed in descending order of Benefit/Cost ratio.

Device	Score	Cost ($K)	Benefit/Cost
Detectors			
BIOHAZ	80	20	**4.0**
LUMINEX 100	71	37	**1.9**
FACSCount	73	59	**1.2**
Identifiers, Immunoassay-based *			
Alexeter BTA (Tetracore tickets)	68	4.5	**15.1**
ANALYTE 2000	46	14	**3.3**
BIOHAZ with New Horizon Tickets	63	20	**3.2**
ORIGEN Analyzer	65	46	**1.4**
LUMINEX 100	52	37	**1.4**
FACSCount	64	59	**1.1**
BioDetector (BD)	66	125	**0.5**
Identifiers, Nucleic acid-based			
CEPHEID SMART CYCLER	46	35	**1.3**
RAPID SYSTEM	57	55	**1.0**

* The Handheld Assays, which scored 80, is not listed because it is a government-furnished product, and the cost must be determined by the responsible government agency.